6-10-02

K021850

3. **510(k) Summary:**

510(k) SUMMARY

Submitter:	Synthes (USA) 1690 Russell Road Paoli, PA 19301
Company Contact:	Matthew M. Hull (610) 647-9700
Name of the Device:	Synthes (USA) 1.3 mm Craniofacial Screws
Classification:	Class II, 21 CFR 872.4880
Common or Usual Name:	Screw, Fixation, Intraosseous
Predicate (unmodified) Device:	Synthes 1.3 mm Self-Drilling Screws, K983485
Device Description:	Synthes Craniofacial screws are available with either self-tapping or self-tapping/self-drilling tips. They are offered in 1.3 mm standard diameter and are also available in a 1.7 mm Emergency diameter. The self-drilling 1.3 mm diameter screws are offered in two variations: cortex and cranial, with the cranial having a slightly greater core diameter and a modified thread profile. The self-drilling screws are offered in 3 – 6 mm lengths and the self-tapping screws are offered in 3 – 18 mm lengths.
Intended Use:	Synthes Craniofacial Screws are intended for selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.
Material:	Titanium Alloy

Special 510(k) Device Modification

4. Device Name:

Synthes 1.3 mm Craniofacial Screws

5. Establishment Registration:

Synthes is registered with the Device Registration and Listing Branch of the U.S. Food and Drug Administration (FDA). This device is manufactured by Synthes (USA), 1101 Synthes Avenue, Monument, CO (FDA Registration No. 1719045).

6. Classification Information:

The classification of the Synthes 1.3 mm Craniofacial Screw is Class II, as per the Code of Federal Regulations, Title 21, Sections 872.4880: "Screw, Fixation, Intraosseous".

7. Information Related to Performance Standards and Special Controls:

These screws will be manufactured from titanium alloy (Ti-6Al7Nb) meeting ASTM F-1295. Synthes is not aware of any performance standards or special controls established to date.

8. Device Description and Comparison:

The modified Synthes craniofacial screws are available in four variants:
1) 1.3 mm craniofacial self-tapping (3-18 mm lengths)
2) 1.3 mm craniofacial self-drilling (3-6 mm lengths)
3) 1.3 mm cranial self-drilling (3-5 mm lengths)
4) 1.7 mm emergency self-tapping screws (3-18 mm lengths)

The new cranial screws have a slightly greater core diameter and a modified thread profile. All the new/ modified screws feature the StarDrive™ drive mechanism and are now made from titanium alloy.

The new/modified 1.3 mm self-drilling screws have slightly larger core diameters than the design previously cleared: 0.95 mm (craniofacial) & 1.01 mm (cranial) versus 0.85 mm. The 1.3 mm craniofacial self-drilling screw is also being offered in a 3mm length. The 1.3 mm cranial self-drilling screw also has a slightly modified thread profile to lower stress concentrations and increase torsional strength. The self-tapping screws are being offered in titanium alloy (TAN) and feature the StarDrive™ drive mechanism while the previously cleared self-tapping screws were manufactured from commercially pure (CP) titanium and utilized a cruciform drive mechanism.

Confidential engineering drawings of the new screws can be found in Attachment 1(a). Drawings of the previously cleared screws can be found in Attachment 1(b). A table describing the modifications made in the Synthes 1.3 mm Craniofacial Screws appears in Attachment 2.

9. Substantial Equivalence:

The new/modified Synthes Craniofacial Screws have the following similarities to the previously cleared screws:

- All have the same indications for use
- All can be used with Synthes Craniofacial and Cranial Plates and Meshes
- All new screws are manufactured from titanium alloy as was the previously cleared 1.3 mm self-drilling screw
- All new screws utilize the StarDrive™ drive mechanism that was utilized by the previously cleared self-drilling screw

The new/modified Synthes 1.3 mm Craniofacial and Cranial Screws have indications that are identical to the previously cleared screws. They are also similar in design, materials and function to the previously cleared device, and therefore, in our opinion, this device is substantially equivalent to the predicate device.

10. Proposed Labeling and Intended Use:

Proposed labels and labeling can be found in Attachment 3. The intended use of the Synthes 1.3 mm Craniofacial Screws is unchanged.

11. Summary of Design Control Activities:

Synthes develops all products in compliance with the Quality System Regulations (21 CFR Part 820). This product was designed and developed according to standard operating procedures and documentation. The risk analysis for this product was developed according to these procedures.

The risk analysis method used to assess the impact of modifications to the 1.3 mm Craniofacial Screws is the Hazards Analysis. Using the Hazards Analysis for the 1.3 mm Self-Drilling Screw as a basis, the revised risk analysis reflects potential risks of the screws, as modified, (see Attachment 4). Potential risks of the 1.3 mm screws have been identified and verification and validation actions have concluded that the potential risks are effectively managed by the stated controls.

Results of verification testing appear in **Table 1** below, which demonstrate that acceptance criteria have been met. Final design review has been conducted and design transfer has taken place in accordance with Quality System procedures.

Table 1: Verification Tests

Concern	Test Performed	Acceptance Criteria	Pass/Fail Results
Insertion torque	MT-98-096 & MT-01-373 (Driving torque of metallic bone screws)	Insertion torque of modified screw design to be equal to or less than predicate.	PASS – Modified screw requires approximately 3.5% less insertion torque.
Maximum torque	MT-98-096 & MT-01-373 (Metallic bone screw torsional properties test)	Maximum torque for the modified screw design to be equal to or greater than the predicate.	PASS – Modified screw showed a 67% increase in torsional strength compared to predicate.

The Declaration of Conformity with Design Controls is located in Attachment 5.

12. Confidentiality Statement

We consider our intent to market this device to be confidential commercial information. Synthes has not disclosed the intent to market this product to others who are not collaborators and consultants. We have taken precautions to protect the confidentiality of our intent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 0 2002

Mr. Matthew M. Hull
Senior Regulatory Affairs Associate
Synthes, (USA)
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K021850
Trade/Device Name: Synthes (USA) 1.3 MM Craniofacial Screws
Regulation Number: 872.4880
Regulation Name: Intraosseous Fixation Screw or Wire
Regulatory Class: II
Product Code: DZL
Dated: May31, 2002
Received: June 5, 2002

Dear Mr. Hull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use

Special 510(k) Device Modification

INTENDED USE STATEMENT

510(k) Number (if known): K021850

Device Name: Synthes 1.3 mm Craniofacial Screws

Indications

Synthes Craniofacial Screws are intended for selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021850